SELECT LEGAL ISSUES, INCLUDING INFORMED CONSENT

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CT Products Regulated by CBER: Effective Strategies to Assist in Product Development

Drugs and Vaccines for the Common Defense: Refining FDA Regulation to Promote the Availability of Products to Counter Biologic Attacks

Gail Javitt, J.D., M.P.H.

19 Journal of Contemporary Health Law & Policy 37 (2002)

ACCELERATED APPROVAL

Drugs: 21 CFR 314.500 – 314.560 "Subpart H"
Biological Products: 21 CFR 601.41 – 601.46

- serious or life-threatening illness
- provide meaningful therapeutic benefit over existing treatments
- surrogate endpoint or clinical endpoint

FAST TRACK PRODUCTS
Section 506 of the FDC Act

- serious or life-threatening condition
- potential to address unmet medical needs
- clinical endpoint or surrogate endpoint

Public Health Security and Bioterrorism Preparedness and Response Act of 2002

ANIMAL RULE

Drugs: 21 CFR 314.600 - 314.650
Biological Products: 21 CFR 601.90 – 601.95

- serious or life-threatening conditions caused by CBRN substances
- unethical or not feasible to study effectiveness
- effectiveness based on animal studies which establish that clinical benefit in humans is reasonably likely

Final Rule (May 2002) 67 Fed. Reg. 37988
Proposed Rule (October 1999) 64 Fed. Reg. 53960
Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (June 2002) Sections 122 and 123

INVESTIGATIONAL PRODUCTS

Section 505(i) of FDC Act

21 CFR Part 312 – IND regulations

- Waiver - 21 CFR 312.10

21 CFR Part 50 - Protection of Human Subjects

21 CFR Part 56 – Institutional Review Boards

- Waiver - 21 CFR 56.105

INVESTIGATIONAL PRODUCTS

A. Treatment IND 21 CFR 312.34 – 312.35
   - serious or immediately life-threatening disease condition
   - no comparable or satisfactory alternative available

B. Open-label Protocol

C. Streamlined IND or Contingency Protocol

INVESTIGATIONAL PRODUCTS

Drugs Intended to Treat Life-Threatening and Severely-Debilitating Illnesses

21 CFR 312.80 – 312.88

- "especially" where no satisfactory alternative therapy exists
- FDA will "exercise the broadest flexibility in applying the statutory standards" of safety and effectiveness
- risk-benefit analysis in review of marketing applications

INFORMED CONSENT

21 CFR 50.25 - basic elements

- description of risks, benefits, and appropriate alternatives

21 CFR 50.27 – documentation

- written consent document or
- short form written consent document

INFORMED CONSENT - exceptions

505(i)(4) FDC Act

- except where it is not feasible or contrary to the best interests

21 CFR 50.23 - exception from general requirements

- life threatening situation
- informed consent cannot be obtained because of an inability to communicate with, or obtain legally effective consent

21 CFR 50.24 – exception for emergency research

- subjects will not be able to give informed consent as a result of their medical condition

BIOSHIELD

H.R. 2122

Section 4 – Authorization for Medical Products for Use in Emergencies

564(b) – Declaration of emergency

564(c) – Criteria for issuance of authorization

564(e) - Conditions of authorization

BIOSHIELD
564(c) – Criteria for issuance of authorization

- CBRN agent can cause a serious or life-threatening disease or condition
- based on totality of evidence, including adequate and well-controlled clinical trials, if available, it is reasonable to believe
  - product may be effective
  - known and potential benefits outweigh known and potential risks
- no adequate, approved, and available alternative

BIOSHIELD
564(a) and 564(l) – 505(i) does not apply

564(e)(1)(A)(ii) – the Secretary, to the extent feasible, given the circumstances of the emergency, shall establish appropriate conditions designed to ensure that individuals to whom the product is administered are informed

- that the Secretary has authorized the emergency use of the product
- of the significant known and potential risks and benefits
- of the option to accept or refuse administration of the product; the consequences, if any of refusing administration; and of alternatives